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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,270	08/05/2005	Christian Krebs	18661-002US2US1/INO10504P	2861

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EXAMINER	
NASSER, ROBERT L	
ART UNIT	PAPER NUMBER
3735	
MAIL DATE	DELIVERY MODE
03/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,270	KREBS ET AL.	
	Examiner	Art Unit	
	ROBERT L. NASSER	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-18,20 and 22-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *43-56* is/are allowed.

6)☒ Claim(s) *14-18, 20, 22, 25-28, 31-37, 39, 41, 42* is/are rejected.

7)☒ Claim(s) *23,24,29,30,38 and 40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14-17, 22, 25-28, 31, 35, 36, 37, 39, 41, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Otterbein et al 2004/0258772. Claim 14 is rejected in that in paragraph [0069] Otterbein discloses the following: an apparatus including a CO source – i.e. a standard tank of gas mixed with carbon monoxide and a dosing unit – Otterbein says the gas can be delivered bedside where it is mixed in a blender. Hence the blender is the dosing unit. In addition, Otterbein in paragraph [0069] discloses a ventilator to deliver the CO to the patient. It also has a sensor means to measure CO in the blood (see discussion of measuring COHB and exhaled CO though side port of the ventilator). Finally, Otterbein has a controller to control the delivery of CO based on the measured values. While the reference does not explicitly describe a controller, it says that the CO exposure can be adjusted based on the patient's health status and on the basis of the markers. Otterbein further describes the above mechanism as a fail safe mechanism. It is the examiners position that in order to function as a fail safe mechanism, the adjustment has to be automatic and therefore Otterbein inherently has a controller. Claim 15 is rejected in that the carbon monoxide is a source of CO in a mixture and the blender mixes the mixture into the breathing gas

of a patient. Claim 16 is rejected in that the delivering unit is a ventilator. Claim 17 is rejected in that Otterbein stats that the CO levels are monitored by measuring the COHb levels AND the CO in exhaled breath. Claims 22 and 25 are rejected in that Otterbein discloses measuring Co by measuring carboxyhemoglobin and CO amount in the expired air. Claim 26 is rejected in that Otterbein shows a method which uses the device of claim 14 that includes administering exogenous CO to a patient, measuring the blood Co concentration, comparing the CO concentration to harmful limit, i.e. a preset desired safety limit, and adjusting the Co levels supplied to the patient if the limits are exceeded. Claim 27 is rejected in that the method if repeated. Claims 28 and 31 are rejected in that Otterbein discloses measuring Co by measuring carboxyhemoglobin and CO amount in the expired air. Claims 35-37 and 42 are rejected for the reasons given above. Claim 39 is rejected in that one of the ways to vary the CO concentration is to add more oxygen to the mixture. Claim 41 is rejected in that since the patient is on a ventilator, the patient is artificially breathing.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otterbein et al. Claim 18 is rejected in it would have been obvious activate an alarm an alarm when the CO concentration exceeded a limit, to alert medical personnel of potential hazardous conditions.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Otterbein in view of Stenzler et al 2004/0084048. Stenzler further teaches using a filter to filter the expiration of a person exposed to CO, to prevent the room air from being contaminated. Hence, it would have been obvious to modify Otterbein to use such a filter, to prevent contamination of the room air.

The examiner notes that Stenzler is an intervening reference and the reference would be overcome if applicant perfected its priority date by supplying a certified translation of the priority document.

Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otterbein in view of Aldrich 5810723. Aldrich teaches measuring carboxyhemoglobin noninvasively with oximetry. Hence, it would have been obvious to modify Otterbein to use such a measurement technique, as it is merely the substitution of one known technique for another.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Otterbein in view of Stone 5293875. Aldrich teaches measuring carboxyhemoglobin spectroscopically. Hence, it would have been obvious to modify Otterbein to use such a measurement technique, as it is merely the substitution of one known technique for another.

Claims 23, 24, 29, 30, 38 and 40 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 43-56 are allowable.

Claims 23 and 29 define over the art in that none of the art monitors Co concentration from levels of oxyhemoglobin.

Claims 24 and 30 define over the art of record in that none of the art monitors CO levels by monitoring enzyme activity in the blood.

Claims 38 and 43-56 define over the art in that none of the art delivers CO to the patient in pulses that are triggered by inhalation or exhalation.

Claim 40 defines over the art in that none of the art delivers Co to the patient in pulses based on the CO concentration.

Applicant's arguments filed 12/19/2007 have been fully considered but they are not persuasive.

With regard to claim 14, applicant has asserted that it is not possible to point out where in Otterbein the claim features are, since Otterbein does not disclose such an apparatus. It response, the examiner notes that indeed he provided applicant with a paragraph number in the previous office action. To clarify the record, the examiner has now pointed out where in the paragraph each of the elements is.

Applicant has asserted that Stenzler is not prior art against the current application. The examiner disagrees. As clearly noted in the prior office action, Stenzler intervenes between applicant's foreign priority date and the PCt filing date. As such, Stenzler qualifies as a reference until applicant perfects the priority claim by filing a certified translation of the German application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3735

RLN
March 17, 2008